K050774

APR 1 1 2005

510(k) Summary Information *Premarket Notification, Section 510(k)*	LANX, LLC. MARCH 21, 2005

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: ***Lanx Anterior Cervical Plate System***

Common Name(s): Anterior cervical spine system

Classification Name(s): Spinal intervertebral body fixation orthosis.

2. *Establishment Name & Registration Number:*

Name: LANX, LLC.
Number: 3004485144

3. *Classification(s):*

§ 888.3060 Spinal intervertebral body fixation orthosis. (a) Identification. A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "sway back", scoliosis (lateral curvature of the spine), or other conditions. (b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): KWQ

4. *Equivalent Predicate Device:*

LANX, LLC. believes that the ***Lanx Anterior Cervical Plate System*** is substantially equivalent to the following:

Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. *Device Description:*

General description of the new plate.

Materials:

Titanium Alloy	ASTM F136-92	ISO 5832-3
Titanium	ASTM F67 GR2-95	ISO 5832-2

Cervical plates are offered for the following levels/configurations. These are the same offerings as detailed in the original submission.
One Level
Two Level
Three Level
Four Level
Five Level

Testing Summary. Fatigue and static testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the new plates perform in a manner equivalent to the previously cleared anterior cervical plates.

6. *Applicant Name & Address:*

Lanx, LLC
1155 Alpine Avenue, Suite 320
Boulder, CO 80304
303-443-7500
Fax: 303-443-7501
fulton@lanx.us

7. *Company Contact:*

Michael Fulton, M.D.
Lanx, LLC
1155 Alpine Avenue, Suite 320
Boulder, CO 80304
303-443-7500
Fax: 303-443-7501
fulton@lanx.us

8. *Submission Correspondent:*

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

LANX, LLC. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. *Storage, Packaging & Sterilization Information:*

The ***Lanx Anterior Cervical Plate System*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The referenced sterilization cycle produces a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:
Method: Steam
Cycle: Gravity
Temperature: 270°F (134°C)
Exposure Time: 30 minutes

All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned.

Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

12. Summary Comparison Table:

FEATURE	*Lanx Anterior Cervical Plate System*	*Modified Anterior Cervical Plate.*	SE?
Indications for Use:	Temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disc disease (neck or radicular pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion.	SAME	YES
Design:	Anatomically curved metallic plate	SAME	YES
Sterile:	No - Must be Autoclaved	SAME	YES
Plate Sizes:	1-level to 5-level 18mm - 118mm length in 2-5mm increments	EQUIVALENT	YES
Material:	Titanium Alloy	SAME	YES
Locking Mechanism:	Manually applied locking mechanism	Intergral locking mechanism – no intra-operative assembly required	NO
Manufacturer:	Lanx, LLC	Lanx, LLC	YES
Product Code:	KWQ	KWQ	YES
K - Number:	K040401	Pending	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

Lanx, LLC
C/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K050774
Trade/Device Name: Lanx Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 20, 2005
Received: March 25, 2005

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050774

510(k) Number : K050774

Device Name(s): ***Lanx Anterior Cervical Plate System***

Indications For Use:

The ***Lanx Anterior Cervical Plate System*** is intended for anterior interbody fixation of the cervical spine. The ***Lanx Anterior Cervical Plate System*** is suitable for use to provide temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disc disease (neck or radicular pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion between C1 and C6.

Warning: This device is not cleared for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use X OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050774

(Per 21 CFR 801.109) (Optional format 1-2-96)